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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,698	UEDA ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,8,12,13,15,17,20 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,31,33,34,36,39-41,46,49,51,61,62,64,66,67 and 69-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,8,12,13,15,17,20,28,29,31,33,34,36,39-41,46,49,51,61,62,64,66,67 and 69-78.

DETAILED ACTION

Applicant's response (along with rule 132 declaration by Takahiro Ueda) and amendments to claims filed on 02/23/2009 is duly acknowledged.

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, 28, 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67 and 69-78 are pending in the application. Claims 63 and 65 have been canceled by applicant's current amendments. Claim 78 is newly added.

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20 and 28 remain withdrawn.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67 and 69-78 (the elected invention of group III, as currently amended) are examined on their merits in this office action.

The following contains new grounds of rejection necessitated by applicant's current amendments to pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67 and 69-78 **are/remain** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 recites the limitation of "a **fat and oil component**" without providing any explicit definition of the term "**fat and oil**" in the instant disclosure (see specification, pages 5-8, in particular) as to how to interpret this limitation as presented in the invention as claimed. Similarly, claim 62 seems to recite said limitation "fat and oil component" in an unclear Markush group containing various exemplifications that includes various types of oils and variety of different fats, which

result in the claimed invention being indefinite. It is not clear if the term "fat and oil" is one component of the composition as claimed, or it requires both fat as well as oil. Appropriate correction is required.

In the absence of any explicit definition of said term, instant claims have been interpreted (for the term "fat and oil") as being met by the presence of any one of the two recited components (i.e. fat or oil) found in a composition in the prior art.

In addition, claim 29, as currently amended by applicants, recites the limitations "**the content of vitamin E**" and "**the content of Tween and/or Span**" in lines 7 and 9 of the claim, respectively. There is insufficient **antecedent basis** for said limitations in the claim. Appropriate correction is required.

Response to Applicant's Arguments

Applicant's arguments (see remarks, page 9, 2nd paragraph, in particular) regarding the use of term "fat and oil" that "*...Those claims, which comprise independent Claims 29 and all others depending therefrom (including new Claim 78), have been amended to define the fat and oil substance of the claimed composition as a component. As such, the 35 U.S.C. § 112 rejection should be withdrawn"* is duly noted. However, it is not clear from the instant disclosure or the argument as filed, if the term represents a fat as "a component", or an oil as "a component", or a mixture having certain ratio of both fat and an oil as "a component". The fat and oil are known to be two distinct materials in the art (i.e. fat is made within the body tissues of living animals, whereas oil is either pressed from plants, as in Olive oil, Corn oil, Peanut oil, Corn oil or Safflower oil, etc., or pumped from the ground as Fossil fuels) and are known to have both physical and chemical differences (for example, at normal room temperature, fats are solid while

oils are liquid), and therefore can not be reasonably taken as being a single component, as currently presented and argued by applicants. In the absence of an explicit definition of said term, the recitation of such limitations is deemed to be ambiguous. Therefore, the rejection of record is properly maintained.

MPEP 2111.05 [R-5] (IV) An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67 and 69-78 (as currently amended) **are/remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (WIPO document, WO 01/52822 A1; IDS) in view of Motoyama et al (US 4,751,241; [A]).

Claims as amended are directed to a "reduced coenzyme Q10-containing composition which comprises reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil component and/or a polyol, wherein the content of vitamin E, **when the same is further contained in the composition**, is lower than 4% by weight based on total weight of the composition minus a weight of coenzyme Q10; and the content of Tween and/or Span species, **when the same is further contained in the composition**, is not higher than 30% by weight based on total weight of the composition minus a weight of coenzyme Q10.

NOTE: In the absence of an explicit definition of the term "fat and oil" as recited in the instant claims, for prior art purposes, claims have been interpreted (for said term "fat and oil") as being met by the presence of any one of the two recited components (i.e. fat or oil) used in a composition disclosed in the prior art.

Chopra (IDS) discloses a reduced coenzyme Q10-containing composition (see abstract, claims, and examples I-X, in particular) comprising reduced coenzyme Q10, a fat or oil, and a polyol (such as glycerol or other polyhydric alcohols). Chopra discloses reduced coenzyme Q10-containing compositions in various forms including oral dosage forms such as soft capsules, etc. which are "substantially ubiquinone-free" (i.e. the oxidized form of coenzyme Q10), and incorporate reducing agents, oils or fat, polyols, and one or more surfactants (see WIPO document, page 14, 5th paragraph, and examples I-X, in particular). Chopra discloses that such Co-Q10 (in an amount from 0.1% to 10% by weight; see Chopra, page 7, and ranges disclosed for examples III and IV, in particular) containing compositions may comprise components such as soybean oil, sunflower oil, safflower oil, rapeseed oil, fish oil, medium chain triglycerides, phospholipids (as recited in instant claim 62; see Chopra, page 12, last paragraph and various embodiments), surfactants (such as Tween 80, 20-90%; or Span 80, 1-15%; see examples I, III, IV, VI, in particular), reducing agent such as vitamin C or ascorbyl palmitate (see Chopra, examples, and claim 2, in particular), **vitamin E acetate, D-alpha tocopherol, or esters thereof**

(in an amount of 2-20%; see page 8, examples II, IV and X, in particular) and can be prepared or stored in a deoxygenated (such as prepared and sealed under nitrogen gas; see Chopra, page 21, example I, last paragraph, in particular).

However, a reduced coenzyme Q10-containing composition comprising **polyglycerol fatty acid ester** (as specifically recited in instant claims 70-72, such as **diglycerol monooleate**), and wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10 (as recited in instant claim 78) is not explicitly taught by the composition of Chopra (IDS).

Motoyama et al [A] discloses polyglycerol fatty acid esters (see abstract, summary of the invention, columns 1-2, in particular) such as diglycerol monooleate (see column 2, lines 23-30, in particular) to be used as emulsifying agents for drugs that are very slightly soluble in water (including ubiquinones, CoQ10; see column 2, lines 38-56, in particular; and also suitable for compositions comprising lipid-soluble reducing agents and/or nutrients such as vitamin E rich natural oils, shark liver oil, etc.) in order to enhance the absorption and thus bioavailability of said drugs (i.e. in a pharmaceutical composition) in the digestive tract when administered using oral dosage forms such as soft capsules (see columns 4-5, and examples), and wherein the content of polyglycerol fatty acid ester used in the composition for increasing the dispersibility of the drug is usually 0.05~30 parts by weight for one part by weight of the drug (see column 4, lines 53-56, and last paragraph; and examples, in particular).

Therefore, it would have been obvious to a person of ordinary skill in the pharmaceutical composition art to modify the reduced coenzyme Q10-containing composition of Chopra (IDS) such that it contains (in addition to the surfactants such as Tween or Span) an emulsifying agent such as polyglycerol fatty acid ester as explicitly taught and exemplified by Motoyama et al.

One of ordinary skill in the art would have been motivated at the time of invention to make such modification in the composition taught by Chopra (IDS) in order to obtain a better reduced coenzyme Q10-containing composition (having an enhanced absorption and bioavailability in the gut) as suggested by Motoyama et al, with a reasonable expectation of success. The limitations, "wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10" would have been obvious to a person of ordinary skill in the art at the time this invention was made as Motoyama et al disclose the suitability of a broad range of concentrations that can be used with a drug that is very slightly soluble in water (such as Co-Q10, and vitamin E containing drugs or nutrients) in order to improve its dispersibility and thus its bioavailability owing to the surface active properties of said polyglycerol fatty acid esters (see column 4, lines 38-42, in particular) when combined with the composition as claimed. The scope of the claimed subject matter, as currently presented by applicants, fails to patentably distinguish over the state of the art as represented by the cited prior art references of record. Therefore, the claims are properly rejected under 35 U.S.C. § 103(a).

With regard to the limitations of claims 33 (content of the fat and oil component and/or polyol, on percent basis), 36 (content of ascorbic acid, on percent basis), 41 (the content of surfactant), 64 (content of reduced CoQ10, on percent basis), and 67 (the content of polyglycerol fatty acid ester by weight, on percent basis), it is to be noted that given the detailed disclosures of all the components and their amounts used for various preparations or dosage forms by Chopra and Motoyama et al (as discussed above), the adjustments to the contents and ratio of various

components used in the composition would have been obvious to a person of ordinary skill in the pharmaceutical formulation art in order to achieve a better and stable composition containing reduced Coenzyme Q10. The claimed limitations of instant claims 46, 49, 51 and 69 are taken to be intrinsic to the composition taught by the cited prior art references, as discussed above.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per PPEP 2144.05 (R-3): In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments (and rule132 declaration from Takahiro Ueda) filed with the office on 03/23/2009 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record:

It is to be noted that instant claims are directed to a composition comprising a "*reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil component and/or a polyol, wherein the content of vitamin E, **when** the same is further contained in the composition, is lower than 4% by weight based on total weight of the composition minus a weight of coenzyme Q10; and the content of Tween and/or Span species, **when** the same is further contained in the composition, is not higher than 30% by weight based on total weight of the composition minus a weight of coenzyme Q10*" (see amended claim 29, in particular).

Applicants argue the following (see remarks, page 10, in particular):

"Since the composition of Chopra contains a large quantity of Vitamin E or Tween/Span, the composition cannot stably maintain reduced coenzyme Q10 without a reducing agent. This is clear from the results of Examples 18-19 and Comparative Examples 3-4 and from the results of Examples 20-22 and Comparative Examples 5-8 in the present specification. Thus, the composition of Chopra stably maintains reduced coenzyme Q10 by using a reducing agent. On the other hand, by incorporating the fat and oil component and/or the polyol, the composition of the claimed present invention can stably maintain reduced coenzyme Q10 whether the composition contains a reducing agent or not."

In response, it is noted that Chopra discloses the range of amounts of vitamin E (2-20%; see example II and III, in particular), and surfactants Tween and/or Span (5-50% Tween, or 0.5-15% Span80; see example IV, in particular) that can be used to stabilize a composition comprising reduced coenzyme Q10. Moreover, the compositions (and the specific amounts) that provided the specific results as pointed out by applicants (i.e. example 18-22 of the instant disclosure) are not currently recited in the claimed invention.

Applicants further argue the following (see remarks, page 11, in particular):

"As shown in the attached Declaration of Takihiro Ueda, the present invention can stably maintain reduced coenzyme Q10 without using a large amount of reducing agent, even though Chopra requires the use of a large amount of reducing agent in order to stably maintain reduced coenzyme Q10. As is clear from the Experiment 1, the composition containing not higher than 30% by weight of Tween80 showed high stability of reduced coenzyme Q10, but the composition containing not higher than 30% by weight of Tween80 substantially inhibited the stability of reduced coenzyme Q10. Thus, when the composition contains higher than 30% by weight of Tween and/or Span, the stability of reduced coenzyme Q10 is different based on the amount of reducing agent used. On the other hand, when the composition contains no higher than 30% by weight of Tween and/or Span, the stability of reduced coenzyme Q10 does not depend on the amount of reducing agent used, and reduced coenzyme Q10 can be stably maintained. However, Chopra neither discloses nor suggest the composition and the excellent effects of the present invention. Therefore, Chopra neither discloses nor suggests that the composition of the present invention can stably maintain reduced coenzyme Q10 by using a fat and oil component and/or the polyol. Furthermore, Chopra neither discloses nor suggests that the addition of the polyglycerol fatty acid ester enhances absorbability of reduced coenzyme Q10 in the living body without inhibiting the reduced coenzymeQ10-stabilising effect of the fat and oil component and/or polyol."

In response, it is noted that the invention as claimed (see claim 29, in particular) does not require a polyol, or vitamin E or surfactants Tween or Span, as currently argued by applicants (i.e. all these components are currently optional). The findings in the declaration that is provided by Takahiro Ueda (see page 2 of the declaration, in particular) is noted and fully considered.

However, the specific components, their amounts, and the ratios used in the experiment showing the surprising results are not currently recited in the invention as claimed. The scope of the claimed invention is not commensurate with the showing presented and currently argued by applicants.

Applicants further argue the following (see page 11):

> "Motoyama et al., on the other hand, relates to a pharmaceutical composition which provides a high degree of bioavailability of cyclandelate when administered orally. The composition consists of a mixture of (a) a polyglycerol ester of an unsaturated fatty acid or mixtures thereof and (b) cyclandelate. Motoyama et al. only describes coenzyme Q10 (ubidecarenone: oxidized coenzyme Q10) on column 2, lines 55-56, and does not describe reduced coenzyme Q10. Thus, since Motoyama et al. uses coenzyme Q10 (which is already oxidized), Motoyama et al. does not intend to maintain reduced coenzyme Q10 stable at all. Furthermore, Motoyama et al. neither discloses nor suggests the effects of the present invention in which reduced coenzyme Q10 is stabilized in the presence of a fat and oil component and/or polyol and the addition of the polyglycerol fatty acid ester hardly inhibits the reduced coenzyme Q10-stabilizing effect of the fat and oil component and/or polyol."

In response, the reference of Motoyama et al has been relied upon in the obviousness rejection of record to demonstrate the fact that, at the time the claimed invention was made, the use of emulsifiers such as diglycerol monooleate (i.e. a polyglycerol fatty acid ester) would have been obvious to a person of ordinary skill in the pharmaceutical art as they clearly suggest the fact that drug formulations comprising drugs that are very slightly soluble in water (including coenzyme Q10, also drug formulations such as vitamin E rich natural oil, etc.) can be stabilized by use of polyglycerol fatty acid esters, which enhance their dispersibility and overall bioavailability *in vivo* (see Motoyama et al, rejection above). Thus, the argument that "*Motoyama et al only describes coenzyme Q10 (ubidecarenone: oxidized coenzyme Q10) on column 2, lines 55-56, and does not describe reduced coenzyme Q10*", is noted. However, it is not found to be persuasive because Motoyama et al disclose compounds or drugs, which are known to be reducing agents and that are very slightly soluble in water (for example, vitamin E

containing nutrients, etc.) that can be suitably stabilized using the polyglycerol fatty acid esters disclosed by them.

Applicants further argue the following (see remarks, page 12):

> "As discussed above, the components other than the polyglycerol fatty acid ester in the composition of the present invention also differ from those in Chopra. Even if Chopra and Motoyama et al. are combined, the specific composition of the claimed invention could not be is unobvious from the combination. The combination would not suggest that the combined could have the good stability of reduced coenzyme Q10 and simultaneously have the high-level absorbability in the living body of the present invention."

The argument is not found to be persuasive because all the components as recited in the claimed composition (i.e. the product as claimed) are explicitly taught and/or suggested and made obvious by Chopra when taken in combination with the disclosure of Motoyama et al (see also the obviousness rejection above), and since the scope of the claims is not commensurate with the showing presented in the form of a declaration from Takahiro Ueda, the composition as claimed remains rejected over the combined teachings of the cited prior art references of record under 35 USC 103(a).

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67 and 69-78 (as currently amended) **are/remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-19 of copending Application No.

11/586,511 (filed in US on 10/26/2006; common inventors; and same assignee, Kaneka Corporation, Japan). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application also claims a reduced coenzyme Q10-containing composition (processed as an oral dosage form) comprising reduced coenzyme Q10, oil and fat, a polyglycerol fatty acid ester, along with a reducing agent, ascorbic acid. Since the two sets of composition claims are co-extensive in their scope, an obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

Applicant's arguments regarding the ODP rejection of record have been fully considered but they are not persuasive for the following reasons of record. Applicants argue the following (see remarks filed on 03/23/09; page 12, 2nd paragraph):

> "With respect to the obviousness-type double patenting rejection, amended Claim 29 contains the limitations of contents of vitamin E and Tween and/or Span. On the other hand, Claim 16 of co-pending application 11/586,511 does not have these limitations. Therefore, it is submitted that the obviousness-type double patenting rejection should be withdrawn"

In response, it is noted that claim 29 of the instant application is directed to a reduced coenzyme Q10-containing composition comprising reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil and/or a polyol, which is deemed generic to the claim 16 of the co-pending application 11/586,511 because said claim 16 recites the limitation of "polyglycerol fatty acid ester with a polymerization degree of glycerol being not lower than 3 and/or a condensed ricinoleic acid polyglyceride", and since vitamin E is disclosed as an art-recognized functional equivalent of vitamin C or its esters (see Chopra, rejection above), therefore, the two sets of claims are still deemed co-extensive in scope, and thus, the provisional ODP rejection of record is properly made and maintained. The use of various emulsifiers (such as polyglycerol fatty acid ester) and surfactants such as Tween and/or Span (alone and/or in combinations) to stabilize reduced coenzyme Q10 containing compositions would have been obvious to an artisan

of ordinary skill in the art based on the combined disclosures provided by Chopra and Motoyama et al (see rejection above), at the time the claimed invention was made.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651